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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,555	07/25/2003	Martin S. Linsell	P-154-US1	3562

27038 7590 08/01/2005  
THERAVANCE, INC.  
901 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

KUMAR, SHAIENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/627,555	Applicant(s) LINSELL ET AL.	
	Examiner SHAIENDRA -. KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.  
     4a) Of the above claim(s) 12-19 and 27-40 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-11 and 20-26 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/7/05 10/7/04 8/9/04, 8/5/04, 7/25/03</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to applicants' communication filed on 4/7/05.

Claims 1-40 are pending in this application. Claims 12-19 and 27-40 stand withdrawn from the consideration, being drawn to the non elected invention.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 4/7/05, 11/17/04, 8/9/04, 8/5/04 and 7/15/03 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Rejections - 35 USC § 103***

2. Claims 1-11 and 20-26 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Moran et al, for the reasons of record.

Instant claims are directed to the Crystalline N-{2-(4-((R)-2-hydroxy-2-Phenylethyl)aminophenylethyl)-(R)-2-hydroxy-2-(3-formamido-hydroxyphenylethylamine dihydrochloride, having certain physical characteristics in terms of X-ray diffraction pattern.

Applicants' arguments were fully considered and were not found convincing. Applicants argue that the Examiner has overlooked the crystalline aspect of the claimed compound, and alleges that no crystalline form has ever been made of this compound having dihydrochloride salt. The examiner would like to point out that the crystalline form is no more than a different physical form of the compound, and a mere different physical nature of the compound is unpatentable, absent evidence to the contrary. Ex parte Hartop 139 USPQ 525 ; In re Cofer 148 USPQ 268. Dihydrochloric acid salt is

obvious over monohydrochloric acid salt, or salt of an acid is obvious over acid. In re Williams, 89 USPQ 396.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHAIENDRA - . KUMAR** whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAIENDRA - KUMAR  
Primary Examiner  
Art Unit 1621

S.Kumar  
6/23/05